

REMARKS

Reconsideration of the rejections set forth in the Office Action mailed June 29, 2004, is respectfully requested. Claims 1-3, 6-10, and 12 remain pending in this case.

Information Disclosure Statement

Applicants gratefully acknowledge that the Examiner has considered the Katz reference and returned the PTO-892 listing this reference.

Interference

With regard to the requirements set forth in 37 CFR 1.607, Applicants respectfully note that a formal request for declaration of interference will be provided upon indication that all pending rejections have been removed. At the present time, such a request is not ripe because the present application remains under rejection. The proposed count will be identical to claim 1 presented herein. It is asserted that claims 1-3 and 6-12 from the present application will correspond to the proposed count. Claims 1-58 from the Macoviak '563 patent will correspond to the proposed count.

The Examiner asserts that the present application has an effective filing date of February 15, 2002, because, according to the Office Action, the priority application, USSN 08/854,806, filed May 12, 1997, does not "specifically disclose 'a filter mesh material of varying porosity.'" Applicants respectfully believe that this assertion is in error for the following reasons. First, the Examiner appears to argue that the written description test would require the instant application to use the exact phrase "a filter mesh material of varying porosity" in order for the application to

be accorded an effective filing date of May 12, 1997. The Federal Circuit has held on many occasions that there is no such requirement. *In re Wright*, 866 F.2d 422 (Fed. Cir. 1989) ("The specification as filed did not include the exact phrase "not permanently fixed," but the original specification disclosure unequivocally taught the absence of permanently fixed microcapsules.") Instead, the priority application meets the written description requirement of section 112 if the priority application demonstrates that the inventors were in possession of the claimed invention at the time the priority application was filed.

In order to show that the priority application demonstrates that the inventors were in possession of the claimed invention at the time the priority application was filed, Applicants submit herewith the Declaration of Richard Murphy. Richard Murphy was formerly employed by EMBOL-X, a former owner of the priority application, USSN 08/854,806. Richard Murphy is a person skilled in the art of intravascular filters, but is not an inventor of the present application. As explained in his declaration, while at EMBOL-X, Richard Murphy worked extensively with filters of the type described in the priority application, USSN 08/854,806.

As explained by Richard Murphy, the filters described in the priority application, USSN 08/854,806 necessarily and inherently meet the requirement of being a filter mesh material of varying porosity. (Murphy Decl., P 4). Moreover, Richard Murphy indicates that, based on his review of the priority application, a person skilled in the technology would understand that the inventors were in possession of the claimed subject matter based on the description in the priority application, USSN 08/854,806, now USPN 6,231,544. (Murphy Decl., P 5).

The priority application, USSN 08/854,806, therefore describes filters having a filter mesh material of varying porosity. The present application is entitled to an effective filing date

of May 12, 1997, which is more than six months before the earliest filing date of Macoviak. Therefore, there is no requirement for Applicants to make a showing under 1.608(b).

Specification

With regard to the term "filter mesh material of varying porosity," please see the discussion above explaining that the inventors were in possession of the claimed subject matter as of the priority documents having an effective filing date of May 12, 1997. This objection should therefore be withdrawn.

With regard to the upstream sealing member being an inflatable toroidal balloon, Applicants note that this feature is described in the '544 patent. For example, each of Figs. 1, 3-8, 9A, 11-13, 29, and 30 show the upstream sealing member being an inflatable toroidal balloon. A person skilled in the art would readily appreciate that, based on these figures, the upstream sealing member of Fig. 27 could be an inflatable toroidal balloon. Moreover, the '544 patent states, at col. 35, lines 36-39, "it will be apparent that certain features of each embodiment, as well as features disclosed in each reference incorporated herein, can be used in combination with devices illustrated in other embodiments." In order to depict each and every combination and permutation of features as proposed by the Examiner would have required hundreds of figures and would have resulted in a rather cumbersome and unwieldy patent. The written description laws make no such requirement. Here, it is plain that the inventors were in possession of the claimed subject matter as of the effective filing date of May 12, 1997. This objection should therefore be withdrawn.

With regard to the assertion that, for the '544 patent, "there is no disclosure of the lumen being configured to be used as a perfusion lumen," Applicants respectfully disagree. Nearly

every figure in the '544 patent, including Fig. 27, depicts an arterial return cannula, designated either by numeral 10 or 350. An arterial return cannula is merely another name for a cannula having a lumen configured to be used as a perfusion lumen. At col. 17, lines 7-8, the '544 patent states, "Blood cannula 10 is adapted to carry blood to the aorta from the bypass-oxygenator system." At col. 22, lines 15-16, the '544 patent states, "Blood cannula 350 is adapted to carry blood to the aorta from the bypass-oxygenator system." This objection should therefore be withdrawn.

With regard to the assertion that the '544 patent does not describe "an occlusion member for selectively occluding said expandable conduit," Applicants respectfully disagree. Each of Figs. 1-11, 19A, 28-30 shows an occlusion member for selectively occluding said expandable conduit. Claim 6 does not require that the occluding member "contact" the expandable conduit. Moreover, even if claim 6 did require that the occluding member "contact" the expandable conduit (which it does not), the '544 patent would still describe an occlusion member for selectively occluding said expandable conduit because this feature is explicitly shown in Fig. 28 of the '544 patent. This objection should therefore be withdrawn.

With regard to the assertion that the '544 patent does not describe "an infusion lumen within said catheter shaft having an infusion port upstream of said occlusion member," Applicants respectfully disagree. In the '544 patent, Fig. 29 and col. 29, line 63 to col. 30, line 18, explicitly describe "a cannula [that] contains an opening 992 proximal to the balloon occluder 65" where "[t]he opening is linked by a conduit 991 which runs along the inside of the cannula and is isolated from the cannula blood flow."

With regard to claim 8, this claim simply requires first and second lumens, one for perfusion and one for infusion. As noted above, Fig. 29 shows "conduit 991 ["first lumen"]

which runs along the inside of the cannula and is isolated from the cannula blood flow ["second lumen"]," and therefore describes first and second lumens, one for perfusion and one for infusion.

With regard to claim 10, which requires "an inflatable occlusion balloon," each of Figs. 1-11, 19A, 28-30 shows an occlusion balloon.

It is important to note the '544 patent states, at col. 35, lines 36-39, "it will be apparent that certain features of each embodiment, as well as features disclosed in each reference incorporated herein, can be used in combination with devices illustrated in other embodiments." Thus, Applicants' arguments with regard to written description are not defeated simply because all the claimed features are not shown together in Fig. 27. The disclosure of the '544 patent plainly demonstrates that Applicants were in possession of the claimed invention as of the effective filing date of May 12, 1997. The present application is not a CIP of the earlier filings. The objections regarding written description should therefore be withdrawn.

Art Rejections

As demonstrated above and as asserted in the oath signed by the inventors, Applicants are entitled to an effective filing date of May 12, 1997. With regard to claim 12, which recites a catheter shaft positioned internal to the expandable conduit, Applicants previously stated that the effective filing date was on December 23, 1997 (see page 13 or Amendment and Response dated March 29, 2004). Upon further review, Applicants have concluded this statement was incorrect and the proper filing date for claim 12 is May 12, 1997 because this feature is shown in the '544 patent in Figs. 1-6, 9, 11, 12, 13, 16, 17, 22-25, and 28-30. Thus, the '544 patent demonstrates that Applicants were in possession of the subject matter of claim 12 as of the effective filing date

of May 12, 1997. Macoviak is therefore not prior art to the present application. The rejection over Macoviak should therefore be withdrawn.

For the above reasons, pending Claims 1-3, 6-10 and 12 are in condition for allowance and allowance of the application is hereby solicited. If the Examiner has any questions or concerns, a telephone call to the undersigned at 949-250-6856 is welcomed and encouraged.

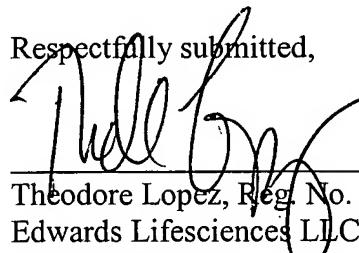
FEES DUE TO FILE THIS AMENDMENT

Prior to the pending Office Action, a fee was paid for the original 23 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and **thus no claim fees are believed to be due to file this amendment.**

PETITION FOR EXTENSION OF TIME TO RESPOND

Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for **Three Months**, or for such other period of time as the Commissioner deems necessary, to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$1,020.00, or any other extension of time fees to Deposit Account No. 50-1225 (Docket No. RMI-5723CON2). A duplicate copy of this sheet is enclosed.

Respectfully submitted,


Theodore Lopez, Reg. No. 44,881
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6856
Facsimile: (949) 250-6850
Customer No. 30452

Date: December 17, 2004

of May 12, 1997. Macoviak is therefore not prior art to the present application. The rejection over Macoviak should therefore be withdrawn.

For the above reasons, pending Claims 1-3, 6-10 and 12 are in condition for allowance and allowance of the application is hereby solicited. If the Examiner has any questions or concerns, a telephone call to the undersigned at 949-250-6856 is welcomed and encouraged.

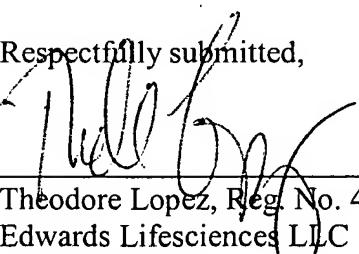
FEES DUE TO FILE THIS AMENDMENT

Prior to the pending Office Action, a fee was paid for the original 23 claims, with 3 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and **thus no claim fees are believed to be due to file this amendment.**

PETITION FOR EXTENSION OF TIME TO RESPOND

Pursuant to 37 C.F.R. 1.136(a), Applicants hereby request an extension of time for **Three Months**, or for such other period of time as the Commissioner deems necessary, to respond to the above-referenced Office Action. The Commissioner is hereby authorized to charge the required fee of \$1,020.00, or any other extension of time fees to Deposit Account No. 50-1225 (Docket No. RMI-5723CON2). A duplicate copy of this sheet is enclosed.

Respectfully submitted,


Theodore Lopez, Reg. No. 44,881
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6856
Facsimile: (949) 250-6850
Customer No. 30452

Date: December 17, 2004